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Total # of Pages 4 (including this page)

TO:	PHONE:	FAX #:
U.S. Patent and Trademark Office Petitions Branch Attn: Karin Tyson	(703) 305 9284	(703) 308 6916

In re Interim Patent Term Extension of U.S. Patent No. 4,373,527

Patentee: Robert E. Fischell

Assignee: The Johns Hopkins University

Issue Date: February 15, 1983

From: Stephen B. Maebius
Sender's Direct Dial: 202 672 5569
Date: November 24, 2000
Client/Matter No: 047711/0100

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Maggie K. McDevitt
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Assistant to Stephen B. Maebius

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#45

Atty. Docket No. 047711/0100

In re INTERIM PATENT TERM EXTENSION OF U.S. Patent No. 4,373,527

Patentee: Robert E. FISCHELL

Assignee: The Johns Hopkins University

Issue Date: February 15, 1983

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PETITIONS OFFICE

SIXTH STATUS INQUIRYAssistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Patentee filed a Status Inquiry on October 13 and 27 and November 3, 10 and 17, 2000, relating to the above-captioned interim extension application. A Request for Reconsideration of Notice of Final Determination of Ineligibility was filed in the U.S. Patent Office on May 8, 2000. The U.S. Patent Office indicated that it is trying to get a response from the FDA to a letter dated March 27, 2000 (copy enclosed), from Ms. Karyn Tyson of the U.S. Patent Office to Mr. David Read of the FDA, so that it can decide how to respond to the Request for Reconsideration. It has more than been 7 months since that letter was sent.

On October 13 and 27 and November 3, 10 and 17, 2000, the patentee filed a status inquiry with the U.S. Patent Office with a copy to Mr. Read at the FDA. On October 19, 2000, the undersigned received a phone call from Ms. Claudia Grillo of the FDA, who indicated that the FDA is in the process of preparing a response to the Patent Office's March 27th letter, and that a response should be complete within a couple of weeks. The patentee hereby requests a status report as to the preparation of the FDA's response.

The patentee is required to file a renewed application for interim extension during a period that starts 60 days before the first year interim extension expires (i.e., such renewed application would need to be filed around December 15, 2000), but in this case, patentee has not yet even been granted the first extension, and the first-year period is drawing to a close.

Respectfully submitted,

NOV 24 2000

Date

FOLEY & LARDNER
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Stephen B. Maebius

Attorney for Applicant
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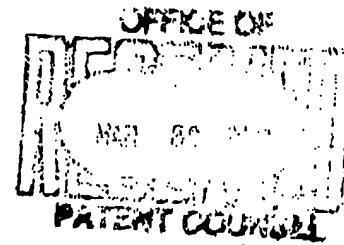
cc: Mr. David T. Read
Acting Director Regulatory Policy Staff, CDEV
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, Maryland 20852



MAR 27 2000

UNITED STATES DEPARTMENT OF COMMERCE
 Patent and Trademark Office
 ASSISTANT SECRETARY AND COMMISSIONER
 OF PATENTS AND TRADEMARKS
 Washington, D.C. 20231

David T. Read
 Acting Director Regulatory Policy Staff, CDEV
 Food and Drug Administration
 1451 Rockville Pike, HFD-7
 Rockville, MD 20852



Dear Mr. Read:

The attached application for interim patent term extension of U.S. Patent No. 4,373,527 was filed on January 28, 2000, under 35 U.S.C. § 156(d)(5).

The assistance of your Office is requested in confirming that the product identified in the application, Minimed 2007, is subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g)(3)(B)(ii).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156(d)(5) only if an application under section 515 of the Federal Food, Drug and Cosmetic Act was initially submitted prior to January 28, 2000 for the product Minimed 2007.

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)872-9411 (facsimile).

Karin L. Tyson
 Karin Tyson
 Senior Legal Advisor
 Special Program Law Office
 Office of the Deputy Assistant Commissioner
 for Patent Policy and Projects

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cc: Francis A. Cooch
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